



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 28 1994

Food and Drug Administration  
Rockville, MD 20857

Docket No. 94E-0332

RECEIVED  
SEP 28 1994  
PM 3:06  
DEPUTY ASSISTANT  
COMMISSIONER FOR PATENTS

#39

Charles E. Van Horn  
Deputy Assistant Commissioner for  
Patent Policy and Projects  
Office of the Assistant Commissioner for Patents  
U.S. Patent and Trademark Office  
Crystal Park Building 2, Suite 919  
Washington, D.C. 20231

Dear Mr. Van Horn:

This is in regard to the application for patent term extension for U.S. Patent No. 4,978,655 filed by Yale University under 35 U.S.C. § 156. The human drug product claimed by the patent is Zerit® (stavudine), which was assigned New Drug Application (NDA) No. 20-412.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). Our records also indicate that it represents the first permitted commercial marketing or use of the product.

The NDA was approved on June 24, 1994, which makes the submission of the patent term extension application on August 19, 1994, timely within the meaning of 35 U.S.C. § 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the Federal Register, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely,

Ronald L. Wilson, Director  
Health Assessment Policy Staff  
Office of Health Affairs

cc: Dominic M. Mezzapelle  
Associate General Counsel-Patents  
Bristol-Myers Squibb Company  
345 Park Avenue  
New York, NY 10154